INTELLECTUAL PROPERTY OFFICE

BL O/365/11

25 October 2011

PATENTS ACT 1977

APPLICANT Dr Harry Nduka

ISSUE Whether patent application GB0818371.7 complies with sections 1(1)(a), 1(1)(b) and 14(5)(c) of the Patents Act 1977

HEARING OFFICER Dr R Dinham

DECISION

Introduction

1 Patent application GB 0818371.7 is entitled "Bladder Sphincter Pacemaker". It was filed on 8 October 2008, although the claims were filed later, on the 21 November 2008. It was published as GB2464152 on 14 April 2010.

2 Throughout the examination process, the examiner has maintained that the invention claimed is not supported by the description, is not clear, lacks novelty or does not involve an inventive step, and may relate to an excluded method of treatment. In response, the applicant, Dr Nduka, submitted various arguments disputing the objections. He also filed an amendment with his letter of 17 May 2011, which the examiner objected to as added matter. These matters were brought before me at a hearing on 31 August 2011. In addition to myself and Dr Nduka, the examiner, Dr Andrew Hughes was also present.

3 After the hearing Dr Nduka presented further observations in an email of 6 September 2011, and I have taken these into account in reaching my decision.

The application

4 The application concerns a device for controlling incontinence using a bladder pressure sensor and a muscle stimulator. In particular, the device is made from an inert material (specified as titanium), and is in three adjoining parts depicted in Figures 1 and 2 below:

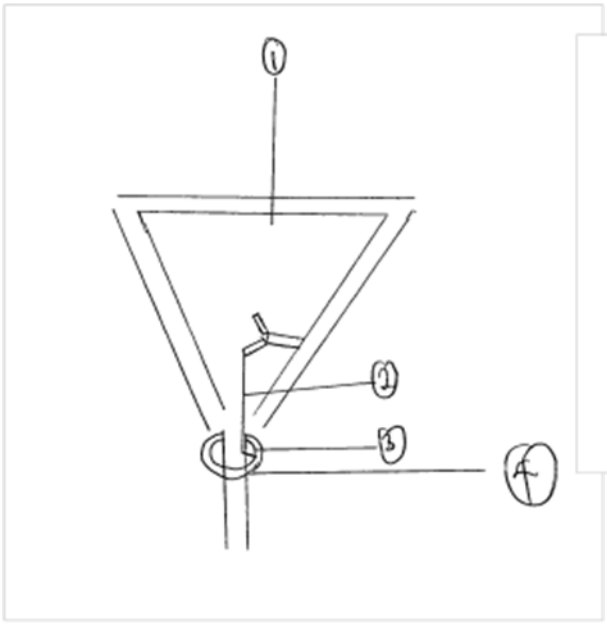

Figure 1

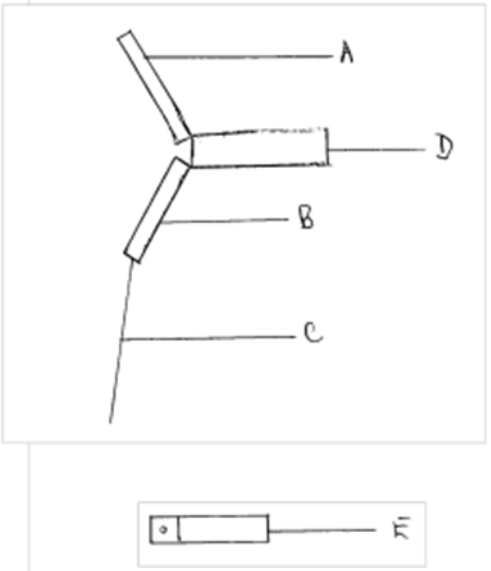

Figure 2

5 The device depicted in figure 2 consists of a calibrated pressure sensor gauge (A), an electrode (B) attached to a guide wire (C), wherein A and B are both attached to one end of an anchor (D) effectively forming a “Y” shape. Also provided is a remote control (E) that operates using radiowaves. Figure 1 depicts the device when in use inside the bladder (1), with the guide wire attaching to the fast twitch muscle sphincter (3) as opposed to the slow twitch muscle sphincter (4).

6 The claims before me were those filed on 21 November 2008. They read:

> *(1) Bladder sphincter pace maker gauging the bladder pressure and stimulating the fast acting sphincter muscle to contract and stop urine leakage.*
>
> *(2) Bladder sphincter pace maker, radio frequency controlled activation of sphincter muscle relaxation to allow passage of urine.*
>
> *(3) Bladder sphincter pace maker pressure gauging adjustability*
>
> *(4) As in claim 1, removable*

Added matter

7 In his letter of 23 July 2011, Dr Nduka stated that the material provided in his letter of 17 May was no longer necessary and therefore did not need to be added to the application. I confirmed this with Dr Nduka at the hearing, and consequently I do not need to consider this matter any further.

The relevant law

8 There are a number of issues outstanding on this application. The examiner has maintained that the invention lacks novelty, inventive step and is not supported by the description. There is also the question of whether the claims could be construed as an excluded method of therapy.

9 Section 1 of the Patents Act 1977 ("the Act") sets out what is required of a patentable invention. It reads:

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) ....

(d) the grant of a patent for it is not excluded by subsections (2) and (3) or section 4A below

10 Section 2 of the Act sets out what novelty means. The relevant subsections (1) and (2) read:

2(1) An invention shall be taken to be new if it does not form part of the state of the art.

2(2) 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.

11 Section 3 of the Act, entitled "Inventive step" reads:

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

12 Section 4A of the Act is entitled "Methods of treatment or diagnosis". The relevant subsection 4A(1) reads:

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)...

13 Section 14 of the Act sets out the requirements that need to be met by a patent application. In particular, the relevant parts of section 14(5) state that:

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;.....

Claim construction

14 Before I begin to discuss the issues outstanding in this application, I feel that I must first explain how the claims to the apparatus of the application should, in my view, be construed. The current claims are not worded clearly and therefore I will make the best interpretation that I can based upon what is disclosed in the description, and what a skilled person would understand these claims to mean if written in plain English. I will therefore make a purposive construction of the claims as per the judgment of the House of Lords in *Kirin Amgen*[1]. At the hearing, and in his subsequent email, Dr Nduka referred to the judgments of Hoffman J in *Improver Corp*[2] , and of Lord Diplock in *Catnic*[3]. Both these judgments are also concerned with the language of the claim, and all three judgments confirm that a purposive construction of the claims should be made.

15 In addition, as the claims could be construed as falling foul of section 4(A) of the Patents Act, I will discuss this patentability issue here and explain how the claims could be interpreted in this regard.

16 Claim 1 as currently worded could be interpreted as a claim to a device *when implanted* in to a bladder, where it has the functionality of gauging bladder pressure and stimulating the fast acting sphincter muscle. As such a use would necessarily involve a surgical step, a claim interpreted in this manner would be excluded from patentability by virtue of section 4(A) of the Act. I have also taken account of the European Patent Office Technical Board of Appeal decision T0775/97[4], which states that a patent cannot be granted for a product claim which is defined by a construction that can only be arrived at in the human or animal body following a surgical method step. In other words, if the claim is to a device that can only be defined in terms of its implantation in the human body, then it will be excluded from patentability.

17 In his email of 6 September 2011, Dr Nduka referred to the judgment of Lord Hoffmann in *Conor v Angiotech*[5] as an example of a patent where a device that was later implanted was not considered to be excluded by section 4(A). However, the claims in the *Angiotech* patent were to the coated stent *per se*, and that it was *suitable for* expanding the lumen or treating restenosis. The patent did not claim the stent when implanted in the body, and therefore was not excluded under section 4(A).

18 Because medical apparatus cannot be claimed *in* situ, i.e. by their location within the body, because this would contravene section 4(A) as discussed above, such

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[1] *Kirin Amgen v Hoescht Marion Roussel Ltd* [2005] RPC 9
[2] *Improver Corporation v Remington Consumer Products Ltd* [1990] FSR 181
[3] *Catnic Components Ltd and another v Hill and Smith Ltd* [1982] RPC 183
[4] T0775/97 EXPANDABLE GRAFTS/ *Surgical device* [2002] EPOR 24
[5] *Conor Medsystems v Angiotech Pharmaceuticals* [2007] RPC 20

claims are construed as the apparatus *per se*. Therefore, I will construe the claim 1 as:- a pacemaker device that is suitable for gauging the bladder pressure and stimulating the fast twitch sphincter muscle in order to stop urine leakage.

19 Appendant claim 4 further defines the pacemaker device as being removable.

20 Claim 2 is construed as a:- pacemaker device that is suitable for providing a radio-frequency controlled relaxation of the bladder sphincter in order to allow the passage of urine.

21 Claim 3 is more difficult to construe due to the unclear wording, and there was some discussion over this during the hearing. Claim 3 is worded as "*a bladder sphincter pacemaker pressure gauging adjustability"*. At the hearing, Dr Nduka asserted that the adjustability related to the movement of the pressure sensor portion of the device, and that this moved as the bladder filled or emptied, and this is how it gauged the pressure. He referred to the original hand-drawn figures, wherein figure 1 depicts a "Y" shaped device, and figure 2 depicts a "T" shaped device. Dr Nduka asserted that this demonstrates the adjustable nature of the position of the pressure sensor in relation to the anchor as a result of the variation in size of the bladder, and that a skilled person would understand the the term "adjustability" to meant just that.

22 At the the hearing I pointed out that the formal drawings provided by (and drawn by) Dr Nduka on 9 January 2009 do not show such a shape difference. In these drawings the device is shown in a "Y" configuration only. Dr Nduka commented that if one measured the angles of the devices depicted in the formal drawings it would be clear that the angles did differ. He referred to the decision of Lord Diplock in *Catnic*[3], and although Dr Nduka's recollection of the facts at the hearing was not identical to those of the *Catnic* case, I think that the point that Dr Nduka was trying to make was that the angles claimed were of significance and that the drawings can be used to interpret the claims. In light of this, according to Dr Nduka, a skilled person reading claim 3, in the context of the drawings and the slight variation in angles of the arms of the device, would understand that the claim related to the moveable feature of the arms.

23 I have studied the drawings in view of what was disclosed in the description as filed. Whilst the hand-drawn figures do show an apparent shape change, this is not replicated in the formal drawings, i.e. those drawings that form part of the published application. This suggests to me that the shape change was not considered to be of technical significance at the date that the application was filed.

24 In addition, the device as drawn appears to consist of three solid portions, which are apparently manufactured from titanium. A solid arm of this sort would only be flexible if it were situated on a hinge or a pivot, yet no such hinge or pivot is disclosed in the specification. Moreover there is nothing in the description that suggests any form of flexibility in the device. In fact, the text accompanying the drawings as filed also states that the "above design allows stability after it is implanted in the bladder". Stability would suggest that it remains in position, or retains its shape. Therefore I cannot see how a skilled person would understand claim 3 to mean that the arms of the device were adjustable in the manner that Dr

Nduka has asserted.

25 Claim 3 has the added complication of being unclearly written. The “pressure gauging adjustability” is confusing due to the use of two verbs together. I have interpreted it to give it the clearest meaning that I can, and in view of what is provided in the description. There is no mention of any moveable feature of the pressure gauge, or of the device in its entirety as it is intended to be attached to the bladder wall via the clamp portion; indeed the only variable feature disclosed in relation to the pressure is the pressure itself.

26 Consequently I consider that a skilled person would read this claim as:- a device for stimulating the bladder sphincter, which has a gauge for measuring the adjustable pressure within the bladder.

27 At the hearing Dr Nduka questioned whether the device would still be excluded if it were to be used only for stimulating the fast twitch muscle *ex vivo*. He also suggested such a use in his email correspondence of 6 September 2011. However, there is no indication in the specification as filed that the device was intended to be used in such a way. In particular, part B of the description states that the action/ function of the device is to prevent urinary incontinence in an individual. Therefore there is no suggestion either explicitly or implicitly that the device was intended to be used for any means other than *in vivo* muscle stimulation, and therefore such a limitation would amount to added matter. In view of this I will not complicate matters by addressing the hypothetical *ex vivo* use.

Approach

28 Having construed the claims, I will now consider the outstanding issues. It makes sense to me to first address the issue of support, as the claims were filed later than the application, and are broader in scope than what is disclosed in the description as filed. The breadth of the claims has a bearing on their novelty and obviousness over the cited documents, and so by considering support first I can then go on to consider novelty in view of what Dr Nduka has claimed and in view of the scope of the patent. I will then address the issue of inventive step.

Support

29 The description filed on the 14 April 2010 was a single hand-written page, accompanied by a single page comprising two drawings. The embodiment described is a bladder sphincter stimulating device of a very specific structure, a Y shaped device as depicted in Figures 1 and 2 reproduced above, which is made from titanium (ie inert) components.

30 Dr Nduka pointed out on several occasions during the hearing that a skilled person would read the claims in light of the description and would realise that they were limited to the embodiment he disclosed. As I emphasised at the hearing, whilst the skilled person would read the description in order to understand what the claims mean, it is the claims themselves that define the part of the invention that one wishes to protect and so their scope must be commensurate with the contribution that the applicant has made to the art.

31 As I construed earlier, claim 1 defines a device that is capable of acting as a bladder sphincter pacemaker, which can gauge the bladder pressure and stimulate the fast acting sphincter muscle to prevent urine leakage. This encompasses any device that is capable of stimulating the fast acting bladder sphincter to prevent urine leakage, regardless of its shape, configuration, composition, or its eventual location in the body. Claim 2 broadly extends to any radio-frequency-controlled device that can relax bladder sphincter muscles to allow the passage of urine, and claim 3 broadly extends to any bladder controlling device that can gauge bladder pressure.

32 The device disclosed in the specification as filed is a very specific device of a very specific configuration, and the claims should be sufficiently narrow to reflect this. In other words, by claiming any device capable of acting as a bladder sphincter pacemaker that can gauge bladder pressure and stimulate the fast acting muscle sphincter, as in claim 1, Dr Nduka is seeking a monopoly for devices beyond the single device that he is entitled to. Claims 2 and 3, which are worded as independent claims, are broader still, and extend the monopoly further. Claim 4, which is appendant to claim 1, states that the pacemaker device is removable. Whilst there was no mention of the removable nature of the pacemaker device in the specification as filed, for arguments sake I will assume that such a feature is implicit. Nevertheless, this feature does not restrict the scope of monopoly sought to the device disclosed in the specification as filed.

33 Consequently, as there is only one very specific embodiment disclosed, I consider that claims 1-4 are unduly broad in scope as they encompass pacemaker devices that are outside of the scope of the invention provided in the specification as filed. Therefore the claims are unsupported.

Novelty

34 In his examination reports, the examiner referred to three pieces of prior art: US2006/247723, US2004/0172087 and US2003/100930. He has based his assessment on the wording of the claims dated 21/11/08, and I will do the same.

35 US2006/247723 discloses a device for controlling bladder function, comprising an electrode, a pressure sensor, and a remote control for voluntary voiding. The electrode is capable of stimulating the sacral nerve, which leads to contraction of the sphincter muscle to prevent urine leakage, and the pressure sensor measures bladder pressure by gauging the variations in pressure on the urinary sphincter of the bladder. The device is made from a biocompatible material, such as titanium, and stimulation (and subsequent muscle relaxation) can be controlled remotely using radiofrequency waves. The device would also be removable. Notwithstanding the fact that when in use the device indirectly stimulates the bladder sphincter muscle through stimulation of the nerve that controls this muscle, it would appear that the electrode is capable of stimulating the bladder sphincter muscle *per se*. Therefore, US2006/247723 comprises all of the features required of claims 1-4 of the present application.

36 The device of US2004/0172087 comprises electrodes for engaging with the bladder sphincter muscle, a pressure sensor for measuring bladder pressure, and a wireless remote control for user control of urination. There is no mention of the

means used for communication between the device and the remote control and therefore I will not assume that it uses radiowaves. Nevertheless, this document comprises all of the features required of claims 1, 2 and 4 of the present application.

37 US2003/100930 discloses a device comprising electrodes that when implanted stimulate pelvic floor muscles, a pressure sensor located on or inside the bladder for measuring bladder pressure, and a remote control unit. This signal between the stimulation part and the control unit does not appear to use radiowaves. Therefore, this document comprises all of the features of claims 1, 2 and 4.

38 Whilst I have considered the claims are currently worded as lacking novelty in view of the prior art documents, given that I have found that the claims lack support, I feel that it would be useful to consider the novelty of the single embodiment disclosed within the specification, should the claims be limited to this embodiment only.

39 It is clear that the general features of the device, such as electrode, pressure sensor, anchor and radio-frequency controlled remote control are all known from one or more of the documents discussed above. In addition US2006/247723 discloses a device consisting of titanium, and therefore this feature cannot be relied upon to impart novelty to the claims. At the hearing, Dr Nduka suggested that the guide wire portion should be claimed in claim 1; however as electroconductive wires that are capable of stimulating the sphincter muscle form part of the devices in each of the documents above, this would also not impart novelty to the claims.

40 At the hearing, Dr Nduka questioned the voltage required for stimulation in order to distinguish the fast twitch muscle from the slow twitch muscle, and asserted that none of the devices disclosed in the cited documents disclosed the voltage required. However, there is nothing in the present application that discloses any specific voltage, or indeed any voltage at all, and therefore this could not be relied upon to provide a novel feature to the present application without contravening section 76 of the Act.

41 However, none of the documents cited disclose a bladder sphincter stimulator comprising an implantable portion and a radio-frequency controlled portion, wherein the implantable portion has the specific Y shape configuration of the present application, and wherein the anchor, sensor and the electrode each form one arm of the Y, and wherein a guidewire is attached to the electrode portion. Consequently none of the documents disclose the specific embodiment disclosed in the description and figures of the specification as filed.

Inventive step

42 As stated above, each of the claims dated 21/11/08 are anticipated by one or more of the three prior art documents identified by the examiner. I will therefore not make an assessment of the inventive step of these claims in view of these cited documents. However, I note that a device of a specific “Y” shaped configuration is not disclosed in any of the prior art documents cited by the examiner, and therefore an amendment along these lines may be non-obvious to

the skilled man.

Decision

43 I have found that the claims on file are not supported by the description, and therefore are unallowable under section 14(5)(c). I have also found that the invention defined in the claims is not new and therefore does not satisfy section 1(1)(a).

44 However, in view of my analysis above, I do consider that that the specification as filed discloses a specific embodiment in the form of the Y shaped device depicted in the figures, and would support a claim(s) limited to such a device. If the claims were limited to such an embodiment, it does not appear that the prior art documents presently cited would anticipate or render obvious such a narrowed claim.

45 Therefore I order as follows:

46 The application is remitted to the examiner for further prosecution and for the filing of suitable amendments.

47 If the amendments are not made by 6 December 2011, the application will be refused for failure to comply with section 18(3).

Appeal

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

Dr R DINHAM
Deputy Director acting for the Comptroller