

Section 2, medical treatment

Claims directed to a method of treatment of a patient's body by stimulation to control body tissue, were replaced by a claim directed to setting a tissue stimulator. The new claim was free of the steps objected to and was found acceptable. Refusal withdrawn.

This decision deals with the Applicant's request for review by the Commissioner of Patents to the Final Action on Application 406,401 (class 326-1.0) filed on June 30, 1982. It is assigned to Neuro Med Inc. and is entitled "Non-Invasive Multiprogrammable Tissue Simulator". The inventor is William N. Borkan. The Examiner in charge issued a Final Action on January 11, 1985 refusing to allow claims 35 to 37 of the application. In response the Applicant cancelled them and proposed a new claim 35, and followed this with further letters of amendment on May 26 and June 16, 1988.

The subject matter of the application relates to an electronic tissue stimulator system having electrodes implanted adjacent tissue to be stimulated in a patient.

In the Final Action, the Examiner refused allowance of claims 35 to 37 as being directed to non-statutory subject matter. That action stated (in part):

Claims 35-37 relate to a method of treatment of a patient's body by stimulation in order to control nerve or muscle tissue. It is not necessary to consider the precise point of novelty over the prior art as this is not a basis for the rejection.

It is noted that Section 2 of the Patent Act does not, in lines 9-13, list a "method" as being included within the scope of the invention, but the term "process" occurs in lines 10, 12 and 36. However, a "process" has been judicially defined as a method step applied to starting materials. In passing, it should be apparent that this analysis is not a mere quibble about the Applicant's choice of wording, but rather directed to the consideration of the subject matter specifically in these claims. In this case, thus, the starting materials comprise a receiver, electrodes, a patient's body and first and second programming data which are subject to certain method steps (of which more below).

The fundamental basis of the rejection will now be clear: the "process", and its final result - a patient's body treated by stimulation, lack any commercial value.

Referring to the method steps, these emphasize that the monopoly sought includes treating the human body by surgery as in "surgically implanting... in a patient", claim 35 lines 2-3 and again at lines 4-6. This surgical intervention, which contradicts some of Applicant's statements, is a part of the fundamental objection above. So also, the method steps of "selecting programming data" require the intervention of a physician and therefore involve the use of judgment and this, too is a part of the fundamental rejection.

...

One point sought to be made by Applicant requires firm rebuttal; on page 3 he says that "The method as defined in claim 35 defines a method of using this machine", and later on "(claim 35) is directed at a new method of using a new apparatus". This is plainly not so, from a strict reading of the claim and even if it were so the claim would still not be patentable because a method of treating a human body is not an industrial process. If Applicant wishes to review the matter further he may find the Manual at Section 12.03.01(c) and (d) to be of some assistance; it indicates that a new instrumentality may be patentable, while the associated process may be unpatentable, because the result depends on a person's judgmental reasoning or personal skill.

In response to the Final Action, the applicant cancelled claims 35 to 37 and submitted a new claim 35. That response stated (in part):

It is noted that both the steps have been deleted from new Claim 35. Although the preamble of the claim points out that the method of Claim 35 is to be used on a tissue stimulator system which has been surgically implanted in a patient, the surgical implantation is recited in the preamble only to set the environment of the claimed subject matter. The surgical implantation step itself is not a part of the claimed subject matter, and it is submitted that having this environment locating statement in the preamble of the claim should not render the claim unpatentable under Section 2 of the Patent Act. It is noted that cancelled Claim 35 did not, in any case, include the tissue stimulation steps. Rather, the steps were included in Claims 36 and 37 which have now been cancelled. It is noted that the statements in Claim 35: "which of said electrodes will be stimulated"; and "a new combination of said electrodes to be stimulated", identify particular electrodes. However, the statements do not define a tissue stimulation step. The selection of electrodes and their polarities do not relate to treatment of the human body until the electrodes are actually stimulated as defined in cancelled Claims 36 and 37.

Accordingly, the method as defined in new Claim 35 relates merely to a method for setting and resetting a surgically implanted tissue stimulator system. As above mentioned, the step of surgically implanting has been removed from the claim so that the claim is no longer objectionable on this ground. In addition, ... the tissue stimulation step is no longer included in Claim 35 so that the claim is no longer objectionable on this second ground.

Further amendments and corrections were made to new Claim 35 by letters dated May 26, 1988 and June 16, 1988. New Claim 35 as amended June 16, 1988, reads as follows:

A method of setting and resetting an electronic tissue stimulator system, comprising at least three electrodes, which has been surgically implanted in a patient, comprising:

- transmitting first programming data, defining which of said electrodes will be stimulated and the electrical polarity of said electrodes relative to one another, to said receiving means to produce a response;
- transmitting second programming data, defining a new combination of said electrodes to be stimulated or a new polarity of said stimulated electrodes, to said receiving means to produce a response.

The issue before the Board is whether or not new Claim 35 is directed to non-statutory subject matter.

We note that the new claim 35 now only recites a method of setting an electronic tissue stimulator system comprising at least three electrodes. Objections made in the Final Action with respect to Claim 35 were to "surgically implanting" and "selecting programming data" which involved the use of judgment on the part of an individual.

New claim 35 no longer contains the steps that were objected to in the Final Action and in our view complies with the requirements of Section 2 of the Patent Act. We recommend acceptance of new claim 35 as amended June 16, 1988.

We note that a question of redundancy with respect to claims 2 and 3 was raised in the Final Action but no rejection was made on that basis. We will make no comment on that issue.



M.G. Brown  
Acting Chairman  
Patent Appeal Board



S.D. Kot  
Member

I concur with the findings and recommendation of the Patent Appeal Board.  
Accordingly, I accept claim 35 as above identified and return the  
application to the Examiner for continued prosecution consistent with the  
recommendation.



J.H.A. Gariépy  
Commissioner of Patents

Dated at Hull, Quebec  
this 24 day of October 1988.

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