Europäisches Patentamt
Beschwerdekammern

European Patent Office
Boards of Appeal

Office européen des brevets
Chambres de recours

Veröffentlichung im Amtsblatt ja/Nein
Publication in the Official Journal Yes/No
Publication au Journal Officiel Oui/Non

Aktenzeichen / Case Number / N° du recours : T 96/83

Anmeldenummer / Filing No / N° de la demande : 79 301 979.5

Veröffentlichungs-Nr. / Publication No / N° de la publication : 0 010 364

Bezeichnung der Erfindung: Transcutaneous Electrical Nerve Stimulator
Title of invention:
Titre de l'invention :

Klassifikation / Classification / Classement : A 61 N 1/36, A 61 N 1/34

ENTSCHEIDUNG / DECISION
vom / of / du 10 July 1985

Anmelder / Applicant / Demandeur : CODMAN & SHURTLEFF INC.

[redacted]

[redacted]

Stichwort / Headword / Référence :

EPÜ / EPC / CBE Art. 52 (1), 123 (2), Art. 56
Inventive step, Amendment to claims

Leitsatz / Headnote / Sommaire

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 96 / 83

DECISION

of the Technical Board of Appeal 3.4.1

of 10 July 1985

Appellant: CODMAN & SHURTLEFF INC.
Pacella Park Drive
Randolph, Massachusetts 02368
U.S.A.

Representative: Colgan, Stephen James et al.
CARPMAELS & RANSFORD
43 Bloomsbury Square
London, WC1A 2RA
United Kingdom

Decision under appeal: Decision of Examining Division 040 of the European Patent Office dated 10 March 1983 refusing European patent application No 79 301 979.5 pursuant to Article 97(1) EPC

Composition of the Board:

Chairman: O. Huber
Member: P. Ford
Member: J. D. Roscoe

I. Summary of Facts and Submissions

I. European patent application No. 79 301 979.5 entitled "Device and method for electronic pain control with scanned output parameters" (original title), filed on 24 September 1979 and published on 30 April 1980 (publication No. 0 010 364) and claiming priority of 26 September 1978 from a previous application in the USA, was refused by decision of Examining Division 040 of the European Patent Office dated 10 March 1983. The decision was based on Claims 1 - 9 received on 26 July 1982. In its decision the Examining Division stated that the feature in Claim 1 and 4 "an output stimulation signal employing a signal amplitude - pulse width-frequency combination which is adequate to produce the requisite pain control effect" (the word "combination" was taken to mean a specific combination) was not suported by the original documents and that, therefore, Claims 1 and 4 included an unallowable amendment and were not acceptable under Article 123 (2) EPC.

II. In the course of the examination the following documents were cited :
US-A-2 350 797
FR-A-2 147 792
DE-C- 970 276 and
CH-A- 577 323

III. On 5 May 1983 the appellant lodged an appeal against the decision. The appeal fee was paid in due time. A Statement of Grounds of Appeal was submitted on 18 May 1983. In a communication on behalf of the Board, the rapporteur cited GB-A-1 488 957.

IV: At the oral proceedings held on 1 March 1985 at the request of the appellant, the appellant's professional representative requested :

- that the decision under appeal be set aside, and
- that a patent be granted.

New documents on the basis of which the grant of a patent is requested were received on
11 March 1985 : Description, p. 2, 3, 5, 12; and on
24 April 1985 : Claims 1 - 8,
Description, p. 1, 3a, 4, 6 - 11,
2 sheets of Drawings 2/3 and 3/3 (Figs. 2A and 2B).

The published sheet of Drawing 1/3 (Fig. 1) is still effective.

V: The independent Claim 1 reads as follows :

A transcutaneous electrical nerve stimulator to be used in pain control comprising :

an oscillator (102) for generating electrical pulses; and an amplifier (109) for amplifying the electrical pulses to produce an output stimulating signal, characterised in that it further comprises :

a frequency modulator (105) for continuously and automatically varying through a range of 50 to 150 Hz the frequency of the electrical pulses;

a pulse duration modulator (106) for continuously and automatically varying through a range of 20 to 150 µsec the pulse width of the electrical pulses; and

an intensity modulator (107) for continuously and automatically varying through a predetermined range the pulse amplitude of the amplified electrical pulses.

II. Reasons for the Decision

1. The appeal complies with Articles 106 - 108 and Rule 64 EPC and is therefore admissible.

2. Present Claim 1 does not contain the amplitude-pulse-width-frequency combination objected to by the Examining Division, c.f. I.

It is therefore incumbent on the Board to examine only whether the claims, in the wording received on 24 April 1985 are supported by the original document. Such examination reveals that the subject-matter of Claim 1 is disclosed in Fig. 1 and the associated parts of the original description, the frequency range and pulse width range mentioned in Claim 1 being specifically referred to on original page 5, l. 16/18. The subject-matter of the present Claim 1 and of the subclaims does not extend beyond the content of the application as filed and the claims meet the other formal requirements of the Convention.

3. GB-A-1 488 957, see Fig. 4, discloses a transcutaneous electrical nerve stimulator (TENS) to be used in pain control comprising an ascillator (20) for generating electrical pulses having a pulse frequency between 10 and 300 Hz (p. 1, l. 90) and a pulse width between 50 and 1000 µsec (p. 1, l. 91/92), and an amplifier (Q_6, Q_7, Q_8 : Q_9, Q_{10}, Q_{11}) for amplifying the electrical pulses to provide a peak amplitude between 10 and 80 mA (p. 4, l. 87). In contrast to the characterising features of Claim 1 the parameters of the applied electrical pulses are manually adjusted (resistor R_3, for frequency, resistor R_{11} for pulse width and resistors R_{15}, R_{16} for amplitude) to predetermined values lying in the above mentioned ranges and not continuously and automatically varied through said ranges.

DE-C-970 276 describes a TENS for use in pain control in which the applied signals consist only of the rectified halfwaves of the alternating mains current and have therefore a fixed frequency of 50 to 100 Hz (p. 1, l. 16). Of the characterising features of Claim 1 only the intensity modulator (24, 32, 34, 37) is disclosed and this continously and automatically varies the amplitude of the second half-wave while leaving the amplitude of the first halfwave unchanged.

US-A-2 350 797, see Fig. 1, describes an apparatus for electro-therapy, especially for artificial innervation of muscles and for use in training of muscles comprising an oscillator (31, 43, 44) and an amplifier (51). Having regard to the physiological differences between transcutaneous electrical nerve stimulation for the purposes of pain control and the application of electrical pulses for therapeutic muscle stimulation, an apparatus suited for the latter is neither identical with one for TENS nor generally suited for TENS. In compliance with parts of the characterising portion of Claim 1 the output pulses are continuously and automatically scanned through a predetermined range of frequency (0,1 - 150 Hz, p. 4, right-hand column, l. 18) by means of a frequency modulator (1, 11) and through a predetermined range of amplitude (0 - 20 V, p. 4, right-hand column, l. 19/20) by means of an amplitude modulator (1, 8). No pulse duration modulator is however provided.

FR-A-2 147 792 also discloses an electrotherapy apparatus, see the title and p. 1, 1/2, as opposed to a TENS for pain control. This apparatus comprises an oscillator (1) for generating pulses, an amplifier (13) and a modulator (19, 21, 22) which automatically and continuously varies the pulse width and pulse frequency in opposite directions to ensure that the value of the energy applied to a patient can be kept below a determined value during the course of a

frequency modulation cycle (30 to 80 Hz during 10 sec, p. 6, l. 25 - 27). There is however no means for an independent automatic variation of the three pulse parameters through predetermined ranges as in the present case.

CH-A-577 323 relates to a physiotherapy apparatus, see the title and col. 1, l. 24 - 32, whereby a direct current and an alternating current (pulses) are simultaneously applied, cf. the main claim. Details of the electric circuit are not shown. The alternating current component has either a low frequency (800 - 3000 Hz, col. 1, l. 7-11, 41, col. 2, l. 13 - 15, Fig. 2E) automatically scanned over a predetermined frequency band or a higher frequency to give a heating action (col. 2, l. 23). In the latter case the frequency or the amplitude is modulated (col. 1, l. 42/43). The current of lower frequency serves as carrier for the current of higher frequency, see col. 2, l. 10 - 12, Fig. 2 F,G.

Thus the TENS, as set out in Claim 1, is new.

4. The question now to be examined is whether the subject-matter of Claim 1 involves an inventive step.

4.1 The most relevant document is GB-A-1 488 957 which represents the state of the art in pain control at the time the present invention was made. The TENS described there only provides for manual adjustment of the three signal parameters (frequency, pulse duration, amplitude). Once adjusted, these parameters remain unvarying until readjusted manually. Problems with such an apparatus are that it is often difficult to obtain the correct combination of the pulse parameters for any situation, and that the patient soon finds that the pain control effect diminishes. According to the description of the application, see page 4, first paragrah, it is therefore an object of the invention to provide a TENS suitable for

pain control which achieves relatively optimum effectiveness for a broad class of nerve types, and also accommodates a relatively broad range of variability in physiological structure of the nerves.

This problem is solved by the characterising features of Claim 1.

4.2 The present invention is based on the understanding that, for any given subject and location and type of pain there will be a particular sort of pulsed electrical signal which will give optimum pain control. It is almost impossible to determine for any subject the optimum pain-controlling signal parameters, although it is possible to assess the general area in which this optimum signal will be found. The TENS according to Claim 1 produces a pain-controlling pulsed electrical signal which varies within the general area in wihch the optimum signal is likely to be found. As the signal varies, it falls at some unpredictable time within the window of sensitivity of the patient.

4.3 Of the other cited documents only DE-C-970 276 relates to a TENS. Having regard to the fundamental technical differences between the circuitry used in the TENS described in GB-A-1 488 957 and that used in DE-C-970 276, cf. 3., the systems are inherently incompatible. Therefore it is not obvious for a person skilled in the art to combine the features of them. Besides, no such combination would lead to the TENS claimed in Claim 1 of the present application because DE-C-970 276 discloses the automatic variation of only the amplitude of the second halfwave of a rectified alternating current, see Fig. 5.

4.4 There is a significant difference between pain control stimulation and muscle control stimulation. Nerve stimu-

a pulse signal having an instantaneous combination of the three parameters (frequency, amplitude, pulse width), whereas muscle control (electrotherapy) requires an on-going and gradual build-up and relaxation of stimulation so as to avoid muscle trauma. In view of this difference between pain control stimulators (TENS) and muscle control stimulators a skilled person looking for an advance in the field of TENS would not as a matter of course look in the field of muscle control stimulators. He would not therefore consider US-A-2 350 797, FR-A-2 137 792 and CH-A-577 323.

4.5 In summary it must be stated that there is nothing in the prior art which would indicate to a skilled person that the problems of finding the optimum pain control conditions and avoiding the diminishing pain control response of a patient could be solved by automatically and continuously varying the three parameters of the signal within predetermined ranges.

4.6 Thus, the TENS in Claim 1 involves an inventive step (Article 56 EPC).

5. Claim 1 is therefore allowable in accordance with Article 52 (1) EPC.

6. Dependent Claims 2 - 8 relate to special embodiments of the invention in Claim 1 and are thus allowable.

7. The effective description meets the requirements of Rule 27 EPC. However on page 3a, line 5, the figure "100" is erroneous and must be replaced by "1000". cf. in GB-A-1 488 957, page 1, line 91, and page 4, line 80.

ORDER

For these reasons it is decided that :

1. The decision of Examining Division 040 of 10 March 1983 is set aside.

2. The case is remitted to the first instance with the order to grant a European patent on the basis of the following documents :

   Description, pages 1, 3a, 4, 6 - 11 received on 24 April 1985 provided that on page 3a, line 5, the figure "100" is replaced by "1000",
   Description pages 2, 3, 5 and 12 received on 11 March 1985,
   Claims 1 - 8, received on 24 april 1985,
   2 sheets of Drawings 2/3 and 3/3 (Figures 2A and 2B), received on 24 April 1985.

The Registrar : The Chairman :

J. Rückerl O. Huber

GD 3
Geschäftsstelle

München, den 26.7.1985

Verteiler: Bezieher von Entscheidungen der Beschwerdekammern

Betrifft: Entscheidung T 96/83 vom 10.7.1985

Bei der übersandten Entscheidungsabschrift fehlt infolge eines technischen Versehens auf Seite 7 die erste Zeile.
Es wird daher gebeten, die ursprüngliche Seite 7 gegen die beiliegende auszutauschen.

J. Rückerl

Anlage

lation for pain control requires periodic application of a pulse signal having an instantaneous combination of the three parameters (frequency, amplitude, pulse width), whereas muscle control (electrotherapy) requires an on-going and gradual build-up and relaxation of stimulation so as to avoid muscle trauma. In view of this difference between pain control stimulators (TENS) and muscle control stimulators a skilled person looking for an advance in the field of TENS would not as a matter of course look in the field of muscle control stimulators. He would not therefore consider US-A-2 350 797, FR-A-2 137 792 and CH-A-577 323.

4.5 In summary it must be stated that there is nothing in the prior art which would indicate to a skilled person that the problems of finding the optimum pain control conditions and avoiding the diminishing pain control response of a patient could be solved by automatically and continuously varying the three parameters of the signal within predetermined ranges.

4.6 Thus, the TENS in Claim 1 involves an inventive step (Article 56 EPC).

5. Claim 1 is therefore allowable in accordance with Article 52 (1) EPC.

6. Dependent Claims 2 - 8 relate to special embodiments of the invention in Claim 1 and are thus allowable.

7. The effective description meets the requirements of Rule 27 EPC. However on page 3a, line 5, the figure "100" is erroneous and must be replaced by "1000". cf. in GB-A-1 488 957, page 1, line 91, and page 4, line 80.