BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS
BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE
CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

File Number: T 149/87-341

D E C I S I O N

of the Technical Board of Appeal 341
of 8 July 1991

Appellant :

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Decision under appeal: Decision of the Opposition Division of the European Patent Office dated 10 February 87 rejecting the opposition filed against European patent No. 0011948 pursuant to Article 102(2) EPC

Composition of the Board:

Chairman: PATERSON G.D.
Members : REICH H J
Himmler U. G.O.M.

Summary of Facts and Submissions

I. The Respondent is owner of European patent No. 0 011 948.

Claim 1 reads as follows:

"1. A programmable cardiac pacemaker pulse generator (16) which is programmed by applying a digital programming signal thereto while maintaining switch means (46) in a disable position from its normally enable position, said programming signal including data manifesting desired operating conditions for said pulse generator to assume, said pulse generator comprising: oscillator means (150) for providing cardiac stimulating pulses; sensing means (42, 170) responsive to the occurrence of natural heart activity for providing a signal to said oscillator means to inhibit the provision of said cardiac stimulating pulses; inhibiting means (190) responsive to said switch means being in said disable position for preventing the provision of said sensing means signal to said oscillator means and means (138BB, 130L, 140) for applying a selected signal to the inhibiting means in response to a programming signal for overriding the inhibiting means and enabling the provision of the sensing means signal to the oscillator means during the programming of certain parameters of said pulse generator which interact with said sensing means."

Claims 2 to 9 are dependent on claim 1.

II. The patent was opposed by the Appellant in particular on the ground of lack of inventive step in view of the prior art which can be derived from documents:

D1: DE-A-2 755 702
D2: DE-A-2 263 834; and
D3: US-A-4 066 086.

III. The Opposition Division rejected the opposition. It took the view that the cited prior art would not suggest the overriding of inhibiting means for the sense amplifier of a cardiac pacemaker during programming in order to allow the observation of the result of a programmed mode having an effect which is only observable by noting the response of the sense amplifier.

IV. An appeal against this decision was lodged by the Opponent, basing the alleged lack of inventive step additionally on the following new documents:

D4: "Instruction for Use: Cordis Corporation, Omni-Stanicor Lithium-Powered, Programmable, R-Wave Inhibited Cardiac Pacer, Model 190, April 1977, page 33; and

D5: "Instructions for Use: Sony Trinitron Colour TV Receiver KV-2202E/2202 ET (1977), pages 4, 5, 38 and 39.

V. Before the Opposition Division the Respondent had inter alia requested rejection of the opposition as inadmissible, since it was not filed in time at the European Patent Office, but at the Berlin sub-office of the German Patent Office. In its decision dated 21 July 1988 the Board referred important points of law concerning the validity and effect of the Administrative Agreement dated 29 June 1981 (OJ EPO 1981, 381) to the Enlarged Board of Appeal under Article 112(1)(a) EPC (Decision T 149/87 dated 21 July 1988; see also OJ EPO 1989, 127 with regard to similar case T 117/87). In the light of the resulting Decisions G 5/88, G 7/88, G 8/88, OJ EPO 1991,

137, the Board took the ~~preliminary~~ view that the Appellant's notice of opposition should be treated as if the EPO had received it in time, and resumed the examination of the appeal.

VI. Oral proceedings were held, during which the Appellant requested that the decision under appeal be set aside and that the patent be revoked.

The Respondent requested that the appeal be dismissed and that the patent be maintained. Admissibility of the opposition was not contested.

VII. In support of his request, the Appellant essentially submitted that claim 1 would lack an inventive step for the following reasons:

(a) The technical field of the opposed patent is a demand mode pacer wherein the R-wave of the natural heartbeat is transformed into an inhibiting signal which resets a counter for inhibiting the delivery of a stimulating pacer pulse and wherein a reed switch actuation by a magnet converts the demand mode into the fixed frequency mode (i.e. a permanent delivery of pacer pulses independent from the appearance of natural heartbeats) in order to check the lifetime of the pacer battery via a noticeable frequency drop of the stimulating pulses at the end of the battery lifetime. The further technical development of such a pacer led to the use of the magnetically closed reed switch for enabling the writing of programm data into a pacer memory, however the enabling of the programming switches simultaneously the demand mode into the fixed frequency mode. Here starts the opposed patent. In order to allow a medical doctor to see the effect of his programming of sense amplifier-dependant parameters, the inhibiting signal is inhibited

a second time. Hence, all the opposed patent would contribute to the prior art is adding a further inverter to the oscillator input. Such a provision of ~~how~~ two subsequent inverters for overriding an inhibiting signal would be obvious to a skilled person in the field of logic circuits, double inversion being known to be used for domestic refrigerators and - according to document D5 - also for TV sets.

(b) The waving of the magnet over the reed switch in document D4 results in a pulse component which has the effect of a second inverter, so that document D4 would describe the same invention as claimed in claim 1 of the opposed patent, with the same purpose to watch the natural behaviour. If a person skilled in logic circuits reads the text of document D4, advising the medical doctor to wave the magnet, it would be obvious to him to replace the waving by another inhibiting gate.

(c) Nothing inventive is to be seen in the aim to watch the interaction of the pacer with the natural heart behaviour. Moreover, whenever a person would like to study this interaction, it would be quite natural to shut the inhibition off.

(d) The wording of claim 1 "during the programming of certain parameters of said pulse generator which interact with said sensing means" would have no exclusive function and only be of explanatory character. Having regard to this feature of claim 1 there would be no difference over the prior art, the waving representing also a programming signal.

VIII. The above submissions were contested by the Respondent, who argued essentially as follows:

(a) The Appellant's general discussion according to paragraph VII (a) above would be based on ex-post-facto analysis. The invention would be more than a double version.

(b) Document D4 does not teach "to override the inhibiting means". The effect of waving the magnet in document D4 is a complete switch-off of the pacer.

(c) Claim 1 is not directed to switch off the pacer for observing the natural heart behaviour but to inhibit the asychronous (fixed frequency) mode in order to study the interaction between the heart and the pacer in operation.

(d) The last words in claim 1 starting with "during the programming" clearly contribute to define the protection sought. However, no objective evidence was presented either showing that the problem - i.e. to override the sense-amplifier disabling effect of the reed switch during programming of sense-amplifier dependent modes - was recognised or contained hints how to achieve this aim. A medical doctor's waving of a magnet would be far remote from the logic circuits applied in the invention.

Reasons for the Decision

1. Though the Respondent has abandoned his objection that the Appellant's notice of opposition should be held inadmissible, the Board points out the following: In view of the Enlarged Board's Decision G 5/88, G 7/88 and G 8/88, OJ EPO 1991, 137, point 3.3, documents which - before 1 July 1989 - were delivered to and accepted by the

German Patent Office in Berlin and which were recorded with a date of receipt, are to be treated by the EPO as if it had received them directly.

In the Board's view, the exclusion of documents filed by hand in answer (ii) of the order of the Enlarged Board's decision is to be interpreted in the light of paragraph 4 of said agreement (which states that the German Patent Office should not accept documents intended for the EPO and brought by hand), as well as point 3.3 of the decision referred to above. The Appellant's notice of opposition was recorded with a date of receipt by the German Patent Office, and is, therefore, deemed to have been filed at the EPO on that very day, pursuant to the said agreement and the Enlarged Board's decision. Accordingly, the opposition is admissible.

2. Documents D4 and D5, which were cited for the first time in the grounds of appeal, have been examined by the Board according to Article 114(1) EPC with the result that they have no influence on the decision to be taken, and ~~can~~ could therefore be disregarded under Article 114(2) EPC.

3. There is no formal objection under Articles 123(2) or (3) EPC to the current version of the claims, description and drawings.

4. Inventive step

4.1 The Appellant concedes implicitly that claim 1 is novel, in particular over document D4; see paragraph VII (b). Thus, the only further substantive issue raised in this appeal is that of inventive step.

4.2 The Board agrees to the Appellant's view in paragraph VII (a) and regards the programmable cardiac pacemaker

represented in document D1 as the nearest prior art. Document D1 discloses in the wording of claim 1:

"A programmable cardiac pacemaker pulse generator which is programmed by applying a digital programming signal (from threshold detector 36; see D1, page 17, paragraph 3) thereto while maintaining switch means (S1, S2) in a disable position from its normally enable position, said programming signal including data manifesting desired operating conditions for said pulse generator to assume, said pulse generator comprising: oscillator means (46, 48, 23 in Figure 4 of D1) for providing cardiac stimulating pulses; sensing means (27 in Figure 4 of D1) responsive to the occurrence of natural heart activity for providing a signal to said oscillator means ~~cardiac stimulating pulses~~ to inhibit the provision of said cardiac stimulating pulses; and inhibiting means (short circuit to ground over S1 in Figure 4 of D1) responsive to said switch means being in said disable position for preventing the provision of said sensing means signal to said oscillator means."

Whenever the pacemaker according to document D1 is programmed - i.e. a programming signal for a higher pulse frequency is entered into the pacemaker - by applying a high magnetic field on magnetic (reed) switch S2, magnetic (reed) switch S1 is simultaneously closed by this field. Reed switch S1 shortcircuits the sensing means signal to ground (first inhibition means). Thus, the sensing means signal cannot arrive at the entry of the "means 35 to inhibit the provision of cardiac stimulating pulses" (second inhibition means). Therefore, during its programming this known pacemaker operates in the fixed frequency (asynchronous) mode and does not react on natural cardiac signals.

4.3 Starting from this nearest prior art as disclosed in document D1, the objective problem underlying the present invention as claimed in claim 1 is to override the disabling effect of the closed reed switch on the sense amplifier during programming when the reed switch has to be closed for enabling the pacemaker to respond to the programming signals, i.e. to allow a person to observe during programming the effect of the natural heart activity on the pacemaker; see the patent under appeal column 3, lines 22 to 27.

4.4 This problem is solved according to claim 1 by providing

(a) a "selected signal ... in response to a programming signal ... during the programming of certain parameters of said pulse generator which interact with said sensing means"; and

(b) "means for applying the selected signal to the inhibiting means for overriding the inhibiting means and enabling the provision of the sensing means signal to the oscillator means" during said programming.

The wording of claim 1 for formulating distinguishing features (a) and (b) is reorganised in the light of the embodiment of the patent under appeal. Functional feature (a) corresponds to the formation of the selected signal in parameter decide logic 138 and functional feature (b) reflects the operation of demand logic 190 under the influence of the selected signal. The Appellant cannot be followed in his view according to paragraph VII (d).

4.5 Conceding that the problem underlying the patent under appeal is obvious, i.e. that a skilled person may notice in practice the need to programm a pacemaker during

the operation of its sensing means and that the necessity to override the (first) inhibiting means (S1) for preventing the provision of the sensing means signal to the oscillator means is a mere logic consequence - see also paragraph VII (a) above - it remains to be examined whether a skilled person can be expected to work out the technical realisation via distinguishing features (a) and (b):

4.6 Document D1 nowhere mentions to integrate into a programming signal of parameters which interact with the sensing means, an override command and to provide within the pacemaker means (138 in claim 1 of the patent under appeal) which "in response to the programming signal" isolate the override stimulus, i.e. the "selected signal" claimed (feature (a)). Document D1 moreover contains no hint to provide in the (first) inhibiting means an entry for an override signal and to reorganise them in order to comprise override means (190A in the embodiment of the patent under appeal) which are activated by this signal, i.e. "to apply the selected signal to the inhibiting means for enabling the provision of the sensing means signal to the oscillator means during the programming (feature (b)).

Document D3 does not come nearer to the subject-matter of claim 1. Document D2 lies further away, dealing with reed switch activated commutation of the pacer pulse voltage.

4.7 All relevant technical teaching of document D4 is contained in the explicit statement: "The implanted pacer can be inhibited by waving or rotating a permanent magnet over the pacer rapidly enough to cause the reed switch to open and close at a rate higher than the fixed rate of the pacer ... to determine the patient's spontaneous rythm". It follows from this statement that the pulse-like

< from the parameter relevant program data >

variation of the magnetic field strength caused by such waving or rotating, represents no "selected signal" as claimed in distinguishing features (a) and (b), i.e. no override signal of (first) "inhibiting means for preventing the provision of a sensing means signal to the oscillator means". This magnetic pulse train rather forms a programming signal which replaces a natural cardiac signal causing a sensing means signal, and takes over the effect of the sensing means signal on the (second inhibiting) "means to inhibit the provision of the cardiac stimulating pulses". In the Board's view, the technical suggestions of document D4 to a skilled person are restricted to the teaching that a pacemaker working in the demand mode, can temporarily be switched off - i.e. inhibited to provide cardiac stimulating pulses - by anticipating and replacing the sensing means signal produced by the natural R-wave via a train of magnetic pulses. Simulating a natural sensing means signal via a person's alternative closure of the reed switch, in the Board's view, does not render it obvious to provide an override signal to the (first) inhibiting means enabling the passage of such a natural sensing means signal to the oscillator. The magnetic pulse train of document D4 thus does not enable but prevents the demand mode. Moreover, this known programming signal contains only one ~~and only~~ control demand; stop the cardiac stimulating pulses.

Also in the device according to document D5 the remote commander sends to the TV set a programming signal with only one control demand at one time: e.g. mute the sound.

For the above reasons late filed documents D4 and D5 are regarded not to influence the decision to be taken.

4.8 As shown in detail above, the cited prior art does not suggest to a skilled person to encode into a programming signal at one time two or more control commands, which have to be effective simultaneously, in particular not a sensing means dependent parameter for the pulse generator plus an override command for the reed switch disabled sensing means. Moreover, there is no hint in the prior art to derive from such a complex informational content of a programming signal, aside from a control command for the pulse generator, a further control command such as the "selected signal" as claimed in distinguishing features (a) and (b). Such technical measures which the Board regards to be defined by the functional formulation of features (a) and (b), allow moreover the restriction of the override effect on the disabled reed switch to a selectable range of parameters, in particular to those interacting with the sensing means. For the above reasons the Board takes the view that distinguishing features (a) and (b) are not the result of a skilled person's use of his general knowledge on logic circuits, and that their creation surpasses the routine capacities of a skilled person.

4.9 For the above reasons, the Board finds that the subject-matter of claim 1 involves an inventive step within the meaning of Article 56 EPC.

5. Hence, it follows that granted claim 1 is maintained. Granted claims 2 to 9 concern particular embodiments of the pacemaker according to claim 1 and are likewise maintained.

Order

For these reasons, it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Beer G.D. Paterson