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D E C I S I O N
of 11 December 2001

Case Number: T 0510/97 - 3.4.1

Application Number: 88114391.1

Publication Number: 0356573

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Language of the proceedings: EN

Title of invention:
Stimulating heart inspection apparatus

Patentee:
Nihon Kohden Corporation

Opponent:
Biotronik Mess- und Therapiegeräte GmbH & Co Ingenieurbüro Berlin

Headword:
Stimulating heart inspection apparatus/NIHON KOHDEN CORPORATION

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (no)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0510/97 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 11 December 2001

Appellant: (Opponent)
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Respondent: (Proprietor of the patent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 4 March 1997 rejecting the opposition filed against European patent No. 0 356 573 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: G. Davies
Members: H. K. Wolfrum
G. Assi

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the decision of the opposition division, dispatched on 4 March 1997, rejecting the opposition against European patent No. 0 356 573. The notice of appeal was received on 7 May 1997, the prescribed fee being paid on the same day. The statement setting out the grounds of appeal was received on 11 July 1997.

II. Opposition had been filed against the patent as a whole and based on Article 100(b) and Article 100(a) together with Articles 52(1), 54 and 56 EPC. The objections concerning sufficiency of disclosure of the invention and novelty were later withdrawn.

III. Oral proceedings were held on 11 December 2001.

IV. The appellant requested that the decision under appeal be set aside and that the patent be revoked. Reference was specifically made to the following documents :

E1: US-A-4 596 255, and

E2: US-A-4 708 142.

V. The respondent (patent proprietor) requested that the appeal be dismissed and that the patent be maintained as granted.

VI. **Claim 1** as granted reads as follows:

"1. A heart stimulation inspection apparatus including stimulation means (1, 20) in which electrical stimulating waves, generated by electrical stimulation

wave generating means (2), for effecting pacing in accordance with an externally set stimulation pattern, are input through a catheter and the intracardiac electrocardiogram signals induced in the catheter are amplified and recorded on a recorder (10, 30) which is connected to the stimulation means (1, 20),
characterized by the following features:
- final stimulation signal generating means (4) which are built-in in either the stimulation means (1, 20) or the recorder (10, 30) and capable of generating a final stimulation signal (a) at a timing corresponding to the final electrical stimulation wave,
- recording start signal generating means (5) which are built-in in the stimulation means (1, 20) and adapted for generating a recording start signal for starting the recorder (10, 30) in advance of the generation of the final electrical stimulation wave,
- recording stop signal generating means (8) which are built-in in either the stimulation means (1, 20) or the recorder (10, 30) and capable of detecting the intracardiac electrocardiogram signal (b) generated for the first time after the generation of the final electrical stimulation wave and generating a recording stop signal after the detection of the intracardiac electrocardiogram signal (b),
- recording control means (12) which are built-in in the recorder (10, 30) and capable of starting the recording paper feed in response to the recording start signal and stopping the recording paper feed in response to a recording stop signal,
- stimulation pattern signal generating means (6) which are built-in in the stimulation means (1, 20) and capable of generating a stimulation pattern signal representative of the stimulation pattern, which is converted into stimulation pattern data (c), and

- recording signal generating means (11) for generating recording signals in accordance with which the waveforms of both the final stimulation signal (a) and the intracardiac electrocardiogram signal (b), and the stimulation pattern data (c) are recorded on the recording paper."

VII. In its decision, the opposition division did not consider any of documents relied on by the opponent to constitute a closer prior art than that discussed in the introductory part of the patent description. In accordance with the patent specification, the objective problem was seen in the desire for conducting a recording automatically for the purpose of eliminating manual control and saving paper. Although the opposition division was of the opinion that the provision of recording start and stop signal generating means as well as of recording control means, *per se*, would constitute standard, everyday constructional practice, the provision of recording signal generating means for the combined recording on paper of the waveforms of the final stimulation signal (a) and the intracardiac electrocardiogram signal (b) together with stimulation pattern data (c) was considered to have no example in the prior art and thus to involve an inventive step.

VIII. The appellant's submissions may be summarised as follows:

The subject-matter of patent claim 1 concerned an apparatus capable of an automatic, real-time printout of the relevant signals and pacing data of a *per se* known heart stimulation inspection procedure. In this context, claim 1 required nothing else than means for

starting the recording by a printer at some time before the delivery of a pacing pulse and for stopping recording some time after the reaction of the heart had been detected. Such a procedure and the technical means required for it were quite conventional. In fact, each of the heart stimulation inspection apparatuses known from documents E1 and E2 made use of a printer. Moreover, both apparatuses detected intracardiac electrocardiogram signals and recorded them on a printer in combination with signals indicative of the occurrence of preceding pacing pulses as well as with data representative of the externally set stimulation pattern. Hence, the subject-matter of claim 1 was rendered obvious by the teachings of documents E1 or E2 either taken alone or in combination.

IX. The respondent disputed the appellant's view, relying on the following arguments:

It had to be taken into consideration that the technology at the filing date in 1988 was far less developed than present-day technology. Thus, it was not permissible to judge the claimed subject-matter on the basis of an ex-post-facto analysis taking into account what might appear conventional on the basis of present-day knowledge. At the filing date, some 13 years ago, an apparatus for heart stimulation inspection which allowed a fully automated, real-time recording on paper of all the relevant information was not available to the physician. As far as recording on a printer was concerned at that time, it was limited to a permanent record of electrocardiogram signals on a continuous strip of paper. The procedure to evaluate the relevant information from a long strip of paper took a long time, was inconvenient and wasted paper. In this

situation, the invention was an apparatus having a specific function, that of restricting the paper record, beginning a short time before delivery of the last pulse of a train of pacing pulses delivered to the heart and ending a short time after detection of an intracardiac electrocardiogram signal. In this context, claim 1 defined the general teaching to which the patentee was entitled whereas details, such as the time scales envisaged, became apparent from the description. In its decision, the opposition division had not given any reasons why it considered the claimed specific means for generating recording start and stop signals to constitute standard, everyday constructional practice nor had it relied on any evidence in support of its view. With regard to the cited prior art, no teaching existed as to a recording on paper in the claimed manner. As a matter of fact, nothing in documents E1 and E2 indicated that start and stop signals for printing were of any interest. E1 taught at best the printing of previously stored data and E2 made explicit reference to conventional strip chart recording.

Reasons for the Decision

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

2. Inventive step (Articles 52(1) and 56 EPC)

2.1 Document E1 (cf. in particular Figures 1 and 4 to 6 with the corresponding description) discloses a heart stimulation inspection apparatus operating in an automated manner and including means, which provide a

display in superposition of atrial or ventricular pulses generated by the pacemaker (such as spikes 51, 53 or indicators 68, 70), electrical signals from within the heart as sensed via the pacemaker (symbolised for instance by "P" or "R"), and data indicative of the circumstances or the type of the stimulation (such as for instance symbols "A" or "V" for atrial or ventricular depolarization pulses, respectively, and indicators such as 68, 70, 74 for time intervals or 82, 84, 92, 94, for programmed refractory periods). The combined display of the various data and signals, which further include an electrocardiogram signal sensed by skin electrodes, occurs in real-time in a time-synchronized manner on a display monitor. Moreover, E1 envisages the recording of data on a supplemental printer which is connected to a controller via memory means.

It follows that the known apparatus comprises a catheter, stimulation means, electrical stimulation wave generating means, final stimulation signal generating means, means capable of detecting the intracardiac electrocardiogram signal, stimulation pattern signal generating means, recording signal generating means, and a recorder of a functionality falling within the terms of claim 1 under consideration. Moreover, as far as the visual display of the signals and data is concerned, the known apparatus comprises recording start signal generating means, recording stop signal generating means and recording control means adapted to provide a display of events starting shortly before the delivery of a stimulation pulse and ending after detection of an intracardiac signal, whereas E1 is silent as to technical details concerning the recording of the data

on the printer.

2.2 Hence, the claimed subject-matter differs from the apparatus according to E1 only in that it requires the recording start signal generating means, recording stop signal generating means and recording control means to be specifically adapted to control the paper feed of the printer for the purpose of obtaining a real-time display on paper.

2.3 In this context, an automatically operating heart stimulation inspection apparatus is known from document E2 which is capable of alternatively monitoring measured pacer system operating parameters and measured patient parameters either by means of a printed record on a plotter or an LCD display (cf. Figures 1 to 3 and 5 with the corresponding description, and in particular column 3, line 67 to column 4, line 2, column 4, line 66 to column 5, line 2, and column 5, lines 26 to 30). For this purpose, the plotter is connected in series to a data processor and a control processor of the apparatus. E2 does not refer in detail to the control signals to be generated for achieving the indicated real-time recording on paper of the various signals and data, which include intracardiac electrocardiogram signals as well as stimulation pattern data, and leaves it to the skills of the expert in the technical field at issue to fill in the missing information.

In the Board's opinion, the skilled person, before the filing date of the present patent, was in a position to devise means providing the necessary control signals for starting and stopping the paper feed of a printer/plotter. It may be noted in this respect that

claim 1 under consideration does not require any specific conditions to be met for the start and stop signals and the corresponding means other than the obvious requirements that the recording should start before the signals of interest occur and stop after the signals have occurred and that the present patent specification as a whole is silent about the technical details of the respective means for generating the recording start and stop signals.

2.4 For these reasons, no exercise of inventive step would have been required for the skilled person to provide a heart stimulation inspection apparatus as known from either E1 or E2 with the means required for an automated, real-time recording on paper of the relevant signals and data and thus to arrive at the subject-matter of claim 1 as granted.

The respondent's request therefore does not comply with the requirements of Articles 52(1) and 56 EPC having regard to inventive step.

Order

For these reasons it is decided that:

The decision of the opposition division is set aside.

The patent is revoked.

The Registrar: The Chairman:

R. Schumacher G. Davies